

Application No.: 09/735173

REMARKS

Applicants' attorney thanks the Examiner for the courtesy of the recent personal interview conducted on June 25, 2003 during which the following issues were discussed.

Claims 25-29 are currently pending. To expedite prosecution and to reduce the number of issues for appeal, claim 29 has been canceled without prejudice and claim 25 has been amended to incorporate subject matter originally encompassed by canceled claim 29. Accordingly, the foregoing amendments should not require any additional searching or raise any new issues.

The foregoing amendments should in no way be construed as an acquiescence to any of the Examiner's rejections, and have been made solely to expedite examination of the present application and to place the pending claims in better condition for appeal. No new issues have been raised and no additional search should be required. Accordingly, Applicants respectfully request that the foregoing claim amendments be entered. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s). No new matter has been added.

Rejection of Claims 25-29 Under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 25-29 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Specifically, the Examiner states that "[a]lthough the instant specification does provide guidance in terms of constructing and testing of a specific bispecific molecule, namely bombesin coupled to mAb22, it does not provide any guidance for any and all bispecific molecules." The Examiner further states that:

[a]lthough it is routine for one of skill in the art to conjugate any growth factor to any antibody or antigen binding fragment, it is not routine experimentation to find any antibody that is able to bind to an Fc receptor at an epitope that is different and distinct from that of an endogenous immunoglobulin. Such determination would require one of skill in the art to perform undue experimentation to practice and make the invention commensurate in scope to the claims.

Applicants respectfully traverse this rejection. However, to expedite prosecution and to reduce the number of issues for appeal, independent claim 25 has been amended to specify that the claimed bispecific molecule comprises an antibody or antigen binding fragment thereof that binds to FcγRI on an effector cell at a site that is not inhibited by endogenous immunoglobulin.

Application No.: 09/735173

The present specification provides more than ample guidance for constructing the presently claimed bispecific molecules. As discussed in Applicants' previous response filed on November 22, 2002, the substance of which is incorporated here, Applicants not only exemplify the necessary steps and procedures for constructing the bispecific molecules encompassed by the claimed invention, but also teach additional art-recognized methods and reagents which can be employed in the exemplified steps and procedures to construct a bispecific molecule comprising an autocrine growth factor specific for a tumor cell and an antibody or antigen binding fragment which binds to an FcγRI receptor on an effector cell at a site that is not inhibited by endogenous immunoglobulin.

In addition, Applicants respectfully draw the Examiner's attention to the following U.S. Patents: (1) 4,954,617; (2) 5,635,600; (3) 6,096,311; and (4) 6,071,517, each of which encompasses antibodies and bispecific molecules that bind to FcγRI at a site that is not inhibited by endogenous immunoglobulin. Therefore, these patents evidence the fact that the knowledge and level of skill in the art at the time of the invention was sufficient alone to have enabled one of ordinary skill in the art to have prepared bispecific molecules that bind to FcγR at a site that is not inhibited by endogenous immunoglobulin. Specifically, U.S. Patent Nos. 4,954,617, 5,635,600, 6,096,311, and 6,071,517 teach methods and techniques for making and identifying antibodies which bind to the FcγRI, and for linking such antibodies to other molecules that bind to target cells. Accordingly, based on the level of skill in the art at the time of the present invention (as evidenced by, for example, by the previously issued patents mentioned above) and the guidance provided within the four corners of Applicants' specification, one of ordinary skill in the art could have made the presently claimed bispecific molecules that bind to FcγRI at a site distinct from the natural ligand binding site, without undue experimentation.

Based on at least the foregoing, the amended claims are fully enabled by the present specification. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 25-29 under 35 U.S.C. §112, first paragraph.

Double Patenting

The Examiner has rejected claims 25-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of U.S. Patent No. 5,833,985.

Application No.: 09/735173

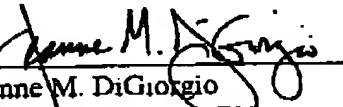
Applicants respectfully traverse this rejection. However, to expedite prosecution, Applicants submit herewith a Terminal Disclaimer which disclaims any portion of the patent issuing from the above-referenced application that extends beyond the patent term of U.S. Patent No. 5,833,985. Accordingly, the rejection is now moot.

CONCLUSION

Applicants respectfully submit that the application is now in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the examiner is urged to call Applicants' Attorney at (617) 227-7400.

Dated: July 14, 2003

Respectfully submitted,

By 
Jeanne M. DiGiorgio
Registration No.: 41,716
LAHIVE & COCKFIELD, LLP
28 State Street
Boston, Massachusetts 02109
(617) 227-7400
(617) 742-4214 (Fax)
Attorney For Applicants